REMARKS

Applicants believe no new matter is added by this amendment. This amendment is being made in response to the pending Office action and was not made previously for that reason.

Status of the claims.

Claims 85-98 are presently rejected. Claims 1-77 were previously canceled. Claims 78-84 are presently canceled. Claims 85, 86, 88, 89, 91-94, 97 and 98 are rejected under 35 U.S.C. § 112, first paragraph, as failing to satisfy the written description requirement. Claims 85-98 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards et al. (July 1998, *Plant Physiol.* 117: 1015-1022) in view of Harada et al (USPN 6,235,975 B1, filed June 24, 1998) and in further view of Edwards (16 September 1997, GenBank Accession no. Y13724).

Response to specific items in the Office action

Item 7. Priority

Applicants reassert their disclosure in US Provisional patent no. 60/125,814 that the sequences provided therein may be transformed into plants to affect their phenotype e.g., claims 1 and 2, to provide useful traits: "In one aspect, the invention provides a recombinant construct which when introduced in a plant alters the phenotype of the plant. Of particular interest, are changes in seed phenotype. Desirable changes in a seed's phenotype include its germination characteristics; shelf-life; drydown characteristics; size; stress responses, such as to heat, cold, *salt or osmotic shock*; protein, oil or starch content; other nutritional content, such as vitamins, minerals, flavonoids, phytosterols or phytic acid; seedling vigor; insect resistance, seed coat quality or the like. Alternatively, the changes may occur in fruit, seeds, roots, flowers, leaves, shoots, seedlings or in combinations of such tissue. And desirable phenotypic changes include increased pest or insecticide resistance, increased plant biomass, resistance to environmental stresses or the like" (60/125,814, beginning at page 1, line 30, *emphasis* added).

Applicants note that Y13724 present in 60/125,814 is the same sequence found in Edwards (Y13724) is indicated as AtHAP3b in Edwards in Fig. 3 in the right-most column), a reference cited against Applicants.

Accordingly, Applicants believe priority application 60/125,814, filed 03/23/99, disclose the sequences, plants, traits, and utility that describe the present invention, that the same sequence, Y13724, is found in the art and priority application 60/125,814, that the latter disclosure provides utility for the sequence and plants transformed with it, and that the date of the art and the priority of the instant application are is less than one year after the cited art.

Item 8. Claim rejection, 35 U.S.C. §112, written description

Applicants respectfully traverse the rejection and its supporting remarks.

Claims 85, 86, 88, 89, 91-94, 97 and 98 are rejected under 35 U.S.C. § 112, first paragraph, as failing to satisfy the written description requirement. Generally, the Examiner indicates that Applicants do not describe polypeptides at least 95% or 98% identical to SEQ ID NO: 4.

However, Applicants note that in order to satisfy the written description requirement of 35 U.S.C. § 112, the application must reasonably convey to one skilled in the art that the applicant was in possession of the claimed subject matter at the time the application was filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). Every species encompassed by the claimed invention, however, need not be disclosed in the specification to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988). The Federal Circuit has made it clear that sufficient written description requires simply the knowledge and level of skill in the art to permit one of skill to immediately envision the product claimed from the disclosure. *Purdue Pharm L.P. v. Faulding In.*, 230 F.3d 1320 1323, 596 USPQ2d 1481, 1483 (Fed. Cir. 2000) ("One skilled in the art must immediately discern the limitations at issue in the claims.").

The "Guidelines for Examination of Patent Applications Under 35 U.S.C.§ 112, ¶1, 'Written Description Requirement" state that a genus may be described by "sufficient description of a representative number of species ... or by disclosure of relevant, identifying characteristics , i.e. structure or other physical and/or chemical properties." *Id.* at 1106. This is the standard for written description set forth in *Regents of the University of California v. Eli Lilly & Co*, 119 F.3d 1559 (Fed. Cir. 1997), where the court held that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, `requires a precise definition, such as by structure, formula, or chemical name' of the claimed subject matter sufficient to distinguish it from other materials." 119 F.3d at 1568, citing *Fiers v. Revel* 984 F.2d 1164 (Fed. Cir. 1993). In *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.2d 926 (Fed. Cir. 2002), the Federal Circuit adopted the PTO standard for written description, stating:

[U]nder the Guidelines, the written description requirement would be met ... if the functional characteristics of [a genus of polypeptides] were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement."

Methods for determining percent identity between any two sequences are well-known in the art and are also provided in the instant specification. Thus, having correlated the claimed functions with structures that are sufficiently known or disclosed (e.g., instantly disclosed and art-recognized CCAAT- box binding conserved B domains), the instant claims directed to methods with polypeptides having at least 95% or 98% sequence identity to the amino acid SEQ ID NO: 4 meet the requirements for written description set forth by the Federal Circuit.

In light of these amendments, and arguments, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, for lack of written description, be withdrawn.

Item 10. Claim rejection, 35 U.S.C. §103(a)

Claims 85-98 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Edwards et al (July 1998, *Plant Physiology* 117: 1015-1022) in view of Harada et al (U.S. Patent 6,235,975 B1, filed 24 June 1998) and in further view of Edwards (16 September 1997, GenBank Accession no. Y13724).

Applicants respectfully traverse the rejection and its supporting remarks, particularly since Applicants, as they have shown, conceived of the claimed transgenic plants prior to the Edwards 1998 publication.

Neither of the references cited by the Office teaches producing and selecting a transgenic plant exhibiting increased tolerance to salt or osmotic stress.

Edwards states that "[t]he expression of AtHAP3b in leaves from plants grown in soil but not in those from liquid culture may suggest environmental regulation of this gene … perhaps in relation to osmotic stress.". The Office suggests that "it would have been obvious to isolate a polynucleotide encoding the complete AtHAP3B gene and transform a plant with the AtHAP3B CAAT-box transcription factor taught by Edwards" and "the characteristic of abiotic stress tolerance would have naturally flown" from the use of the transcription factor.

In fact, this is not the case. Edwards does not suggest making a transgenic plant overexpressing AtHAP3b, and for good reason. Edwards was published about the same time as Harada et al. and Lotan et al, and as shown below the latter publications teach away from the instant claims and provide a disincentive to combine the references to grow plants that have improved salt or osmotic stress tolerance (said traits would naturally exclude seeds).

The accepted wisdom provided by Harada et al. or Lotan et al. (see below) is that LEC1, and homologous sequences that may function together with LEC1, including HAP3 CCAAT-binding proteins, function at the embryo stage but not beyond. That one must proceed contrary to this accepted wisdom by combining Harada with the sequences of Edwards is evidence of nonobviousness.

Harada is a *significant* teaching away from the instant claims since greater salt or osmotic stress tolerance cannot be envisaged if CCAAT-binding proteins, as represented and taught by Harada with LEC1, are embryo-specific (Harada, col. 1, line 17) and repress the germination process (Harada, col. 27, line 63). The claimed functions of salt and osmotic stress tolerance are characteristics of plants grown beyond the plant embryo stage. Knowledge that LEC1, which is taught by Harada to be related to HAP3 proteins (e.g., see

Harada's Fig. 2a) is embryo-specific and represses the germination process would direct the skilled artisan away from sequences that are taught to be inoperable with respect to the instantly claimed traits, including the instant sequences that are, allegedly, sufficiently related to LEC1 to merit an obviousness rejection. Thus, Edwards and Harada, alone or in combination, do not provide a motivation to practice the instantly claimed methods.

Immediately after the Harada filing, Lotan et al. *Cell* (June 26, 1998) 93: 1195-1205 (the authors include inventors of 6,235,975 B1; Lotan was submitted with the IDS of 03-04-2005) also taught that "LEC1 appears to function as a specific regulator of embryo development" (page 1200, col. 1), "LEC1 RNA accumulates only during seed development in embryo cell types and in endosperm" (abstract) since "expression studies showed that the LEC1 gene is active only within seeds during both early and late seed development" (page 1196, col. 1). When the LEC1 gene was overexpressed, "T1 seeds germinated with an efficiency of only 0.006%, much less than the 1% efficiency typically obtained from in planta transformation experiments. …Their roots often did not extend or extended only in sections and sometimes greened" (page 1200, col. 1-2). Lotan et al. also believe that "the LEC1 polypeptide is homologous to the HAP3 subunit of the CBF class of eukaryotic transcriptional activators that includes NF-Y, CP1, and HAP2/3/4/5" (page 1201, col. 1) and that this "high degree of sequence conservation in the B domain strongly suggests that LEC1 is part of an oligomeric [CCAAT box–binding factor] transcription activator". Thus, Lotan et al. and Harada et al. suggest that LEC1 functions with CCAAT box–binding factors (e.g., instant SEQ ID NO: 2), but the role of LEC1 is only within seeds, and thus cannot confer a role in salt or osmotic stress tolerance. Furthermore, ectopic expression of LEC1 produced roots that did not extend or extended only in sections, which would also teach away from improved salt or osmotic stress tolerance since poorly extended roots would be highly unlikely to improve tolerance to these stresses. Given the failure of these authors and inventors to produce healthy plants overexpressing a sequence that was reportedly expressed only in seeds, where the plants have a very poor germination efficiency and poorly extended roots, the combination of Harada and Edwards to produce salt or osmotic stress tolerant plants fails to provide any suggestion or motivation to practice the instantly claimed methods. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention. *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968).

In view of the amendments to the claims and the arguments presented above, Applicants respectfully request that the rejection under 35 U.S.C. §103(b) be withdrawn.

CONCLUSION

Applicants believe that no additional fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Mendel Biotechnology, Inc. Deposit Account No. **50-1025.**

Respectfully submitted,
MENDEL BIOTECHNOLOGY, INC.

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